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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,417	01/09/2004	Rainer Hammann	P-5917	6382

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/753,417	HAMMANN ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, Claims 1-12, in the reply filed on 1/24/05 is acknowledged. Claims 13-16 are withdrawn from further consideration.

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. The disclosure is objected to because of the following informalities: On page 12, section 0028 Applicant states the following "strains were obtained from clinical sites and the ATCC (ATCC strains were used for internal QC) and prepared. Applicant has failed to identify the complete strain identifier.

Appropriate correction is required.

The use of the trademark CHROMagar™ on page 11, section 0025 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims lack the step of showing how the resistance is determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al (U.S. Patent Application Publication 2002-0076742 A1)

Claims 1, 10-11 are drawn to a method of detecting antibiotic resistant microorganisms, comprising administering at least one β-lactam antibiotic to said microorganisms, wherein said β-lactam antibiotic is not oxacillin.

Chen et al discloses a method of detecting the presence of target microbial microorganisms in a biological sample and determining the susceptibility of such microorganisms to antimicrobial agents. One compartment comprises medium that is capable of sustaining the growth of the total microbial agents. Chen et al discloses in example 8 (page 9, section 0080) that each well contains media capable of sustaining the growth of a gram-positive organism as well as antibiotics. Chen et al further discloses the method of presenting a sample into each well where the results would indicate the presence of a pathogen from the Staphylococcus spp. group which is resistant or non-resistant to the test antibiotic (page 9, section 0082). Chen et al discloses that the target microbial microorganisms can be *Staphylococcus aureus* among others (page 2, section 0014). Lastly, Chen et al discloses specific test media to test the antimicrobial efficacy of cephalothin, cephradine and cephalexin among others (page 5, section 0040).

4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Merlino, J. et al (New chromogenic identification and detection of *Staphylococcus aureus* and Methicillin-Resistant *S. aureus*, Journal of Clinical Microbiology, June 2000; 38(6): 2378-2380).

Claims 1-6 are drawn to a method of detecting antibiotic resistant microorganism, comprising at least one β-lactam antibiotic to said microorganisms, wherein said β-lactam antibiotic is not oxacillin. In addition the claims are drawn to the method of claim 1, wherein the administration comprises culturing said microorganism in or on a chromogenic agar medium for *S. aureus*, said chromogenic agent is selected from the group consisting of 5-bromo-6-chloro-3oindoxyl phosphate and 5-bromo-4-chloro-3 indoxyl glucoside, said chromogenic agar further comprises at least one β-lactam antibiotic that is not oxacillin.

Merlino et al discloses a method of detecting *Staphylococcus aureus*. The method comprises administering 4μg of methicillin to an agar screening plate. Merlino et al discloses that of the 114 *S. aureus* isolates tested on CHROMagar all grew and were identified chromogenically as *S. aureus* (page 2379). Merlino et al does not teach a chromogenic agar medium where at least one chromogenic agent consists of 5-bromo-6-chloro-3-indoxyl phosphate or 5-bromo-4-chloro-3 indoxyl glucoside. The claim limitation of consisting of 5-bromo-6-chloro-3-indoxyl phosphate or 5-bromo-4-chloro-3 indoxyl glucoside would be inherent in the teachings of the prior art because the method of the prior art uses the same CHROMagar as taught by the instant specification (page 11). Inherently, the CHROMagar would have at least one of the

chromogenic agents as claimed. Lastly, Merlino et al disclose that methicillin resistance was confirmed by the detection of penicillin-binding protein 2a (page 2378).

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merlino, J. et al (New chromogenic identification and detection of *Staphylococcus aureus* and Methicillin-Resistant *S. aureus*, Journal of Clinical Microbiology, June 2000; 38(6): 2378-2380) as applied to claim 1-6 above in view of Felten et al (Evaluation of three techniques for detection of low-level methicillin-resistant Staphylococcus aureus (MRSA): a disk diffusion method with cefoxitin and moxalactam, the vitek 2 system and the MRSA-screen latex agglutination test, J. Clin. Microbiology, 2002; 40(8): 2766-71).

Claims 1-12 are drawn to the method, wherein the administration comprises culturing said microorganism in or on a chromogenic agar medium for *S. aureus*, said chromogenic agent is selected from the group consisting of 5-bromo-6-chloro-3-indoxyl phosphate and 5-bromo-4-chloro-3 indoxyl glucoside, said chromogenic agar further comprises at least one β-lactam antibiotic that is not oxacillin.

Merlino et al discloses that 126 staphylococcal isolates were examined. These included *S. aureus* among others (page 2378). Merlino et al further discloses that of the 114 *S. aureus* isolates tested on CHROMagar all grew and were identified chromogenically as *S. aureus* (page 2379). Lastly, Merlino et al disclose that methicillin resistance was confirmed by the detection of penicillin-binding protein 2a (page 2378). . Merlino et al does not teach cephalosporins such as cefoxitin.

Felten, F. et al teaches a method of detecting methicillin-resistant *Staphylococcus aureus* (MRSA) using cefoxitin. Felten et al teach that 100% of the MRSA were detected using the method (abstract). It would be obvious at the time the invention was made to substitute the methicillin as taught by Merlino et al with the cefoxitin of Felten et al in the method of detecting MRSA because Felten et al teach that cefoxitin is more sensitive and specific for detection of MRSA (page 2769). It would have been expected barring, evidence to the contrary, that the cefoxitin would improve the detection of MRSA since the prior art teaches that cefoxitin is a suitable alternative for oxacillin in routine antibiotic susceptibility testing.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT

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